

(iii) Apply safeguards against unnecessary utilization of services; and

(iv) Develop procedures for utilization review, and establish groups to perform such reviews of providers to whom it makes Medicare Part B payments.

(g) *Information and reports.* The carrier must furnish to HCFA any information and reports that HCFA requests in order to carry out HCFA's responsibilities in the administration of the Medicare program. The carrier must be responsive to requests for information from the public.

(h) *Maintenance and availability of records.* The carrier must maintain and make available to HCFA the records necessary for verification of payments and for other related purposes.

(i) *Hearings to Part B beneficiaries.* (1) The carrier must provide an opportunity for a fair hearing if it denies the beneficiary's request for payment, does not act upon the request with reasonable promptness, or pays less than the amount claimed.

(2) The hearing procedures must be in accordance with part 405, subpart H, of this chapter (Review and Hearing Under the Supplementary Medical Insurance Program).

(j) *Other terms and conditions.* The carrier must comply with any other terms and conditions included in its contract.

[45 FR 42183, Jun. 23, 1980; 45 FR 64913, Oct. 1, 1980, as amended at 49 FR 3660, Jan. 30, 1984; 49 FR 9174, Mar. 12, 1984; 51 FR 34833, Sept. 30, 1986; 51 FR 41350, Nov. 14, 1986; 51 FR 43198, Dec. 1, 1986; 52 FR 4499, Feb. 12, 1987; 53 FR 6648, Mar. 2, 1988; 54 FR 4027, Jan. 27, 1989; 57 FR 27307, June 18, 1992]

#### § 421.201 Performance criteria and standards.

(a) *Application of performance criteria and standards.* As part of the carrier evaluations mandated by section 1842(b)(2) of the Act, HCFA periodically assesses the performance of carriers in their Medicare operations using performance criteria and standards.

(1) The criteria measure and evaluate carrier performance of functional responsibilities such as—

(i) Accurate and timely payment determinations;

(ii) Responsiveness to beneficiary, physician, and supplier concerns; and

(iii) Proper management of administrative funds.

(2) The standards evaluate the specific requirements of each functional responsibility or criterion.

(b) *Basis for criteria and standards.* HCFA bases the performance criteria and standards on—

(1) Nationwide carrier experience;

(2) Changes in carrier operations due to fiscal constraints; and

(3) HCFA's objectives in achieving better performance.

(c) *Publication of criteria and standards.* Before the beginning of each evaluation period, which usually coincides with the Federal fiscal year period of October 1-September 30, HCFA publishes the performance criteria and standards as a notice in the FEDERAL REGISTER. HCFA may not necessarily publish the criteria and standards every year. HCFA interprets the statutory phrase "before the beginning of each evaluation period" as allowing publication of the criteria and standards after the Federal fiscal year begins, as long as the evaluation period of the carriers for the new criteria and standards begins after the publication of the notice.

[59 FR 682, Jan. 6, 1994]

#### § 421.202 Requirements and conditions.

Before entering into or renewing a carrier contract, HCFA determines that the carrier—

(a) Has the capacity to perform its contractual responsibilities effectively and efficiently;

(b) Has the financial responsibility and legal authority necessary to carry out its responsibilities; and

(c) Will be able to meet any other requirements HCFA considers pertinent, and, if designated a regional DMEPOS carrier, any special requirements for regional carriers under § 421.210 of this subpart.

[45 FR 42179, June 23, 1980, as amended at 57 FR 27307, June 18, 1992]

#### § 421.203 Carrier's failure to perform efficiently and effectively.

(a) Failure by a carrier to meet, or demonstrate the capacity to meet, the criteria and standards specified in

## § 421.205

§ 421.201 may be grounds for adverse action by the Secretary, such as contract termination or non-renewal.

(b) Notwithstanding whether or not a carrier meets the criteria and standards specified in § 421.201, if the cost incurred by the carrier to meet its contractual requirements exceeds the amount that HCFA finds to be reasonable and adequate to meet the cost which must be incurred by an efficiently and economically operated carrier, those high costs may also be grounds for adverse action.

[59 FR 682, Jan. 6, 1994]

## § 421.205 Termination by the Secretary.

(a) *Cause for termination.* The Secretary may terminate a contract with a carrier at any time if he or she determines that the carrier has failed substantially to carry out any material terms of the contract or has performed its function in a manner inconsistent with the effective and efficient administration of the Medicare Part B program.

(b) *Notice and opportunity for hearing.* Upon notification of the Secretary's intent to terminate the contract, the carrier may request a hearing within 20 days after the date on the notice of intent to terminate.

(c) *Hearing procedures.* The hearing procedures will be those specified in § 421.128(c).

## § 421.210 Designations of regional carriers to process claims for durable medical equipment, prosthetics, orthotics and supplies.

(a) *Basis.* This section is based on sections 1834(a) and 1834(h) of the Act which authorize the Secretary to designate one or more carriers by specific regions to process claims for durable medical equipment, prosthetic devices, prosthetics, orthotics and other supplies (DMEPOS). This authority has been delegated to HCFA.

(b) *Types of claims.* Claims for the following, except for items incident to a physician's professional service as defined in § 410.26, incident to a physician's service in a rural health clinic as defined in § 405.2413, or bundled into payment to a provider, ambulatory surgical center, or other facility, are

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processed by the designated carrier for its designated region and not by other carriers—

(1) Durable medical equipment (and related supplies) as defined in section 1861(n) of the Act;

(2) Prosthetic devices (and related supplies) as described in section 1861(s)(8) of the Act, (including intraocular lenses and parenteral and enteral nutrients, supplies, and equipment, when furnished under the prosthetic device benefit);

(3) Orthotics and prosthetics (and related supplies) as described in section 1861(s)(9);

(4) Home dialysis supplies and equipment as described in section 1861(s)(2)(F);

(5) Surgical dressings and other devices as described in section 1861(s)(5);

(6) Immunosuppressive drugs as described in section 1861(s)(2)(J); and

(7) Other items or services which are designated by HCFA.

(c) *Region designation.* The boundaries of the four regions for processing claims described in paragraph (b) of this section coincide with the boundaries of 1 or more sectors or areas designated for the Common Working File. These four regions contain the following States and territories: Region A: Maine, New Hampshire, Vermont, Massachusetts, Connecticut, Rhode Island, New York, New Jersey, Pennsylvania, and Delaware. Region B: Maryland, the District of Columbia, Virginia, West Virginia, Ohio, Michigan, Indiana, Illinois, Wisconsin and Minnesota. Region C: North Carolina, South Carolina, Kentucky, Tennessee, Georgia, Florida, Alabama, Mississippi, Louisiana, Texas, Arkansas, Oklahoma, New Mexico, Colorado, Puerto Rico and the Virgin Islands. Region D: Alaska, Hawaii, American Samoa, Guam, the Northern Mariana Islands, California, Nevada, Arizona, Washington, Oregon, Montana, Idaho, Utah, Wyoming, North Dakota, South Dakota, Nebraska, Kansas, Iowa and Missouri.

(d) *Criteria for designating regional carriers.* HCFA designates regional carriers to achieve a greater degree of effectiveness and efficiency in the administration of the Medicare program as measured by—